

### **REMARKS/ARGUMENTS**

Claims 15-28 are currently pending in the application. The present reply includes amendments to claims 15 and 26. Reconsideration of this application and entry of the amendments after final are respectfully requested.

The amendments place the claims in better form for appeal. Additionally, the amendments address items brought up by the examiner in the final office action.

By these amendments, Applicant does not acquiesce to the propriety of any of the Office's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 USPQ.2d 1865 (US 1997). Furthermore, Applicant reserves the right to file continuing applications directed to the subject matter of any claim amended or cancelled for any reason.

In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

#### **I. 35 U.S.C. § 103 Rejections**

Claims 15-28 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over United States Patent No. 6,835,759 ("Bradford") or United States Patent No. 6,162,511 ("Garnett"). Office Action mailed October 21, 2008 ("OA"), page 2. Applicant respectfully traverses.

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a

suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

#### A. Bradford

According to the Office's characterization of Bradford, the Office concludes that,

it would have been obvious to one having ordinary skill in the art to select the relatively high and low molecular weight polymeric species, the unsaturated monomer such as acrylic acid or a diacrylate, a UV activatable compound such as benzophenone, polyvinylpyrrolidone as a coating additive, and a suitable solvent to formulate a coating composition suitable for coating on an implantable medical device as presently claimed, motivated by the reasonable expectation of success.

OA, pages 3-4. Applicant respectfully disagrees with the Office's characterization of Bradford and its conclusions based on the same. Nonetheless, and solely to expedite prosecution of the pending claims, Applicant has amended claims 15 and 26 to recite that the coating formulation is suitable for coating on an implantable biomedical device with only one curing step at room temperature. Support for this amendment can be found within the specification as filed and at, for example, paragraphs [0047] and [0065].

Bradford does not teach or suggest a coating formulation suitable for coating with only one curing step. Instead, Bradford states that the coatings it discloses are "dual cure." As defined therein, dual cure refers to "curable coating compositions that require exposure to both electromagnetic radiation and heat to achieve the degree of crosslinking necessary to achieve desired performance properties." Bradford, Col. 4, l. 66 – Col. 5, l. 3. In examples 2-6, Bradford states, "[t]he UV cured panels for each

sample were then thermally cured in a gas oven at a temperature of 250°F for 20 minutes (part temperature) and allowed to cool.” Bradford, Col. 23, ll. 10-13; Col. 24, ll. 1-3. Thus, the coatings of Bradford require two distinct curing steps. Accordingly, Bradford does not teach or suggest all of the pending claim limitations and as a result cannot render them obvious under 35 U.S.C. § 103(a).

#### B. Garnett

Based on the Office’s interpretation of Garnett, the Office concludes that, “one having ordinary skill in the art would have readily envisage selecting the claimed components in the forming a coating composition suitable for coating on an implantable biomedical device, motivated by the reasonable expectation of success.” OA, pages 4-5. Applicant respectfully disagrees with the Office’s characterization of Garnett and its conclusions based on the same. Nonetheless, and solely to expedite prosecution of the pending claims, Applicant has amended claims 15 and 26 to recite that the coating formulation is suitable for coating on an implantable biomedical device with only one curing step at room temperature. Support for this amendment can be found within the specification as filed and at, for example, paragraphs [0064] and [0065]. The present application also states as a drawback of the prior art that, “[i]n all of these coating systems elevated temperature and aggressive solvents or surface pretreatment are necessary to effect attachment of the coating to the device.” Paragraph [0006].

Garnett does not teach or suggest a coating formulation suitable for coating an implantable medical device at room temperature. In fact, Garnett teaches away from applying coatings at room temperature. Particularly, Garnett states,

Some substrates after being treated by conventional processes on line are quite hot at the end of the treatment (for example in the range of from 100 to 150°C). In many of these applications, UV coatings cure very efficiently and with excellent adhesion if applied at elevated temperatures i.e. immediately on line at the completion of the polymerisation process when the product emerges from the oven. The adhesion is generally far superior to room temperature application followed by UV cure on the same substrates. ... In this technique the substrate undergoes a prior, non-related thermal treatment or the like at the completion of which, whilst still

on line a UV curable coating is applied hot and passed under the appropriate curing UV lamp system. ...

In accordance with this embodiment the invention therefore provides a method of coating as hereinbefore described wherein the substrate is also heated preferably to a temperature in the range of 50 to 200°C and more preferably 50 to 150°C and most preferably 70 to 150°C. The advantages of applying a radiation curable coating to a hot substrate are particularly great where the substrate is a styrene polymer resins particularly those incorporating glass fibre. ... The reaction to form the polymer is exothermic so that the product after processing has a temperature of about 100 to 150°C. We have found that extremely good adhesion is provided if the coating composition is applied to the styrene polymer product before cooling. ...

The invention in one preferred embodiment therefore provides a method of forming a coated styrene polymer or copolymer product, particularly styrene polyester, comprising forming the product by exothermic polymerisation to provide a hot formed product and applying a radiation curable coating to the hot formed product (preferably at a temperature the range of from 50 to 150°C. (more preferably 70 to 150°C) and curing the coating by subjecting it to radiation.

Garnett, Col. 7, l. 54-Col. 8, l. 43 (emphasis added). Thus, the coatings of Garnett require application at an elevated temperature. Accordingly, Garnett does not teach or suggest all of the pending claim limitations and as a result cannot render them obvious under 35 U.S.C. § 103(a).

Based on the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the pending rejections of claims 15-28 under 35 U.S.C. § 103.

### **CONCLUSION**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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